# AdvaMed's Written Testimony for the Reauthorization of the Medical Device User Fee and Modernization Act

AdvaMed is pleased to submit this written testimony. AdvaMed, the Advanced Medical Technology Association, represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion health care technology products consumed annually in the United States, and nearly 50 percent of $159 billion purchased around the world annually.

## Executive Summary

In summary, AdvaMed believes that the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA) is good for patients and for the public health. It will facilitate the timely and effective review of new medical technologies and bring them to patients as soon as those products can be shown to meet the necessary rigorous FDA requirements. It also ensures that FDA's medical device program will be on sound financial footing. FDA's device program needs sufficient funding to do its job in a timely way, and this bill will ensure that the agency has that funding for the next five years. We believe this legislation strikes a proper balance: stable and predictable funding for the FDA that is tied to continued incremental improvements in performance and important enhancements to the review process including more transparency and more interaction between FDA reviewers and applicants. This bill is the product of a year-long discussion between the agency and the device industry, and we are pleased that, today, the entire medical device industry and the FDA stand united, together, in support of this legislation.

Background

This legislation builds on experience gained from the implementation of the original medical device user fee program which was enacted in 2002. That program helped FDA bring important new technologies to patients sooner while maintaining the high standards needed to demonstrate safety and effectiveness. That is the bottom line. The medical device industry continues to be on the cutting edge of new technology development. We recognize the important statutory role the Food and Drug Administration (FDA) plays in reviewing the scientific basis for new device products prior to marketing. Therefore, we believe it is important that FDA have the necessary resources to fulfill that statutory function in a sound, effective, and efficient way.

We are pleased that MDUFMA made important strides towards accomplishing that goal. Over the past five years, FDA has received significant increases in funding for the device review program, including necessary funds for the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA). This funding came from a combination of user fees and increased appropriations. With these added funds, the agency has been able to hire and train additional staff as well as enhance its information technology systems. The result is that the agency has, to date, met the quantitative performance goals outlined in the "goals letter" accompanying MDUFMA. That is good news because it means patients are getting more rapid access to the newest, proven technologies.

To build on that successful start, over the past year, AdvaMed, together with our colleagues in the Medical Device Manufacturers Association (MDMA) and the Medical Imaging Technology Alliance (MITA, formerly NEMA), have been working with FDA over the past year to create a reauthorization package that would strengthen this program still further. AdvaMed

believes it is very important that we as an industry are united in support of this bill and that, together, we are united with the FDA on its contents, from start to finish.

We are very encouraged that the Senate has recently passed, overwhelmingly, a MDUFMA II bill that incorporates all the essential elements we agreed to with the FDA. We hope that the House acknowledges the value of the MDUFMA II agreement and works toward swift passage in the House of Representatives.

Key Provisions of User Fee Bill

Key elements of this legislation and the accompanying implementation commitments of the FDA include the following:

1. Increased Funding that is Stable and Predictable First, this legislation would provide FDA with a stable and predictable funding mechanism for the device program, through a combination of appropriations and user fees. In fact, under MDUFMA II, the user fee revenues to be collected over 5 years would increase approximately 90% over those collected during the previous 5 years under MDUFMA I. Importantly, the legislation continues a central provision of the original MDUFMA legislation whereby Congress is committed to providing FDA's device program with an annual inflationary increase. The user fees the industry pays will be additive to the appropriated Congressional base. Under MDUFMA I, all of FDA's revenue from user fees was derived from application fees. As a result, FDA's revenue was unpredictable and led to insufficient revenue in years in which fewer applications were submitted. To address this fluctuation in revenues, FDA and industry have agreed to a new fee structure that combines existing application fees with a new facility registration and annual report fees. These fees will ensure that FDA has a more stable and predictable revenue stream. The new fee structure also

includes limits on the amounts that application fees can increase from year to year. These limits are important to prevent the significant fluctuations in fee levels that industry experienced in the early years of MDUFMA I. Additional funding provided in MDUFMA II will also allow FDA to train its reviewers to enhance their scientific expertise.

2. Significant improvements for small businesses. This legislation contains significant improvements for small businesses, the lifeblood of so much innovation within our industry. The new fee structure provides further reductions in application fees for small businesses, as compared to what larger companies would be required to pay. This will provide an important incentive for innovation and will help ensure the viability of this vital sector of our industry. In addition, the process enhancements that FDA plans to implement such as a more interactive review process, will also provide greater benefits to those small businesses.

3. Quantitative Performance Goals. Quantitative performance goals for FDA's review of new medical device applications were an important component of MDUFMA I. We commend FDA for the modified goals included in MDUFMA II. The agency has committed to review each application type within a specified time period. These performance goals have improved the overall efficiency and predictability of the review process that is essential for industry. We are also pleased that the agency has agreed to continue making incremental improvements in the timeliness of its new product application reviews. For the first time, FDA will complete the review of the most sophisticated new devices in less than 300 days, under the premarket approval application (PMA) process, and FDA action on breakthrough devices (those device applications qualifying for "expedited review") will be completed even sooner. Finally, we are pleased that FDA has agreed to revamp and simplify the performance goal structure to focus on the time for final "decision goals" rather than on intermediate "cycle goals." Taken

together, we believe these goals will make the review process more predictable and more efficient, without compromising the high level of rigor necessary to ensure the safety and effectiveness of new medical devices.

4. Qualitative Goals. We are pleased that FDA has agreed to a number of qualitative goals as well. Most important is the agency's commitment to an interactive review process. An interactive review process will increase review efficiency and improve communication between reviewers and applicants. This will establish a more dynamic and efficient mechanism to obtain clarifications or readily available information needed to complete the review process. To facilitate this process, FDA has agreed to develop guidance to its reviewers and industry, based on the principles we have outlined. FDA has also agreed to take a number of steps to increase the clarity around a number of issues affecting the review of in vitro diagnostic products (IVDs) and combination products. Finally, we are pleased that FDA has agreed to work with industry to identify and develop priority guidance documents that provide companies with clearer insights into what the FDA expects to see in new applications for different categories of devices.

5. Third Party Inspection. This legislation would also make needed adjustments to the current third party inspection program authorized under MDUFMA I. These procedural adjustments will make it feasible and attractive for eligible companies to participate in the program while maintaining the stringent conflict of interest requirements for third party inspectors and the stringent eligibility requirements for participating companies. FDA's authority to inspect a facility at any time also remains unchanged. We are pleased that FDA is committed to making this program work. This program will allow FDA to focus its inspectional resources in a risk-based manner and better focus its limited inspectional resources. At a time

when everyone's resources are limited, it is important that FDA-accredited third parties are fully utilized.

6. Pediatric Device legislation. Last week, the Senate also passed legislation by Senator Dodd designed to address the challenges facing pediatric medical device development. We commend Senator Dodd and others who worked on the Senate legislation for their efforts and look forward to working with Congressman Markey and Congressman Rogers on their bill, the Pediatric Medical Device Safety and Improvement Act. Our industry is committed to the goal of providing children access to life-saving, life-enhancing medical devices. At the same time, it is equally critical that we prevent the unintended consequence of adversely impacting the availability of safe and effective medical devices for the broader population.

As we attack the problem of limited availability of pediatric devices for children, we need to address the root causes – lack of knowledge of pediatric needs and lack of incentives. The market for pediatric uses is often very limited, while the cost of development and regulatory clearance or approval can be comparable to the adult market. Unlike drugs, the kinds of incentives that exist in the Best Pharmaceuticals for Children Act are not available to the device industry. Creating incentives such as improvements in the pediatric HDE program, establishing a new compassionate use pediatric device provision, using existing regulatory mechanisms to facilitate device clearance and approval without reduced safety and efficacy standards for children, or creating tax credits or grant programs for companies developing pediatric devices could improve pediatric device access.

We thank Congressmen Markey and Rogers and Congresswoman Eshoo for their leadership on pediatric issues. We look forward to working with the Committee on this important priority.

Conclusion

We believe the reauthorization of MDUFMA that incorporates all the essential elements industry and the FDA have agreed to will enable FDA to further improve its performance—in both quantitative and qualitative ways—while creating a stable and predictable fee structure that benefits both FDA and the device industry. Most importantly, American patients will be the true beneficiaries because of their access to new and innovative medical technology. Advamed would like to thank both our industry colleagues and the FDA staff who worked so diligently over the past year to reach this point. AdvaMed again calls on the Committee work swiftly towards passage.